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**U. S. Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
February 25, 2003**

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## **Charm SL Beta-lactam Test (M-I-03-3)**

TO: All Regional Food and Drug Directors  
Attn: Regional Milk Specialists

FROM: Milk Safety Branch (HFS-626)

SUBJECT: Charm SL Beta-lactam Test

The Food and Drug Administration's (FDA) Center for Veterinary Medicine (CVM) has evaluated data supporting the use of the Charm SL Beta-lactam test for raw, commingled goat milk.

The FDA evaluation of the data, presented by Charm Sciences, Inc., indicates that the performance of the test meets the standards established to determine the acceptance of a test for use in raw commingled goat milk. The acceptance of the test for raw commingled goat milk represents an extension of a claim as the test has previously met the standards established for acceptance of screening tests for monitoring raw, commingled milk in accordance with the provisions of Appendix "N" of the Grade "A" Pasteurized Milk Ordinance.

FDA and the NCIMS Executive Board accept the use of this test when used as labeled. Attached is the letter of acceptance from FDA's CVM.

Copies of this memorandum are enclosed for distribution to Regional Milk Specialists, State Milk Regulatory Agencies, State Laboratory Evaluation Officers and State Milk Sanitation Rating Officers in your region. This memorandum will also be available on the FDA Web site at <http://www.cfsan.fda.gov> at a later date and should be widely distributed to State Veterinarians, State Veterinary and Pharmacy Boards, Veterinarian Professional Organizations, and representatives of the dairy industry and other interested parties.

Attachment: Charm SL<sup>™</sup> Beta-lactam Test for Amoxicillin, Ampicillin, Ceftiofur, Cephapirin and Penicillin G-Operator's Manual for Raw, Commingled Bovine or Goat Milk

CAPT Robert F. Hennes,  
RS, MPH  
Chief, Milk Safety  
Branch

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Date November 18, 2002  
From Philip James Kijak, Ph.D.  
Subject Addition of a Claim for Goat Milk to the Charm SL Beta-Lactam Test  
To Robert F. Hennes, Milk Safety Team

An evaluation of the Charm SL Beta-Lactam test kit for Amoxicillin, Ampicillin, Ceftiofur, Cephapirin and Penicillin G in Goat Milk has been completed. Representatives of the NCIMS Other Species committee requested Charm Science to conduct an evaluation of the SL Beta-Lactam Kit for goat milk. The testing was conducted at an independent laboratory, DQCI Services Inc. Jackson-Mitchell, a goat milk dairy in California, provided the funding, control goat milk and incurred goat milk for the study. Charm Sciences provided the test kits and coordinated the work. The protocol for the study was reviewed and approved by CVM. The testing protocol was based the CVM "PROTOCOL FOR EVALUATION OF MILK RESIDUE SCREENING TESTS WITH GOAT MILK", not dated.

Several modifications to the protocol were made. For each of the five drugs, a modified dose response curve was generated which exceeded the requirements of the CVM goat milk protocol. The summary of the results are as follows (number of Positive/Total Samples)

<b>Concentration ppb (part per billion)</b>	<b>Amoxicillin</b>	<b>Ampicillin</b>	<b>Ceftiofur</b>	<b>Cephapirin</b>	<b>Penicillin G</b>
1					1/10
2	5/10	0/10			11/15
3					30/30
4	23/30	0/10		1/10	30/30
5					30/30
6	30/30	0/15			
8	15/15	21/30		11/15	
10	30/30	30/30	0/10		
12				29/30	

16				29/30	
20			0/10	30/30	
30			3/15		
40			26/30		
50			30/30		

The testing was done in three groups, with 60 control samples in each group. Because of problems with the initial set of data for ampicillin, CVM recommended that the testing for this compound be repeated. An additional set of 60 control samples were assayed during the repeated experiment. For all four sets of 60 control samples tested, no false positive responses were observed. The data in the table for ampicillin is based on the repeated experiment.

For the incurred samples, only three animals were dosed for each of the three required drugs for both early and late lactation instead of the ten required in the CVM protocol. This change was allowed because reducing the number of animals used for incurred milk would not compromise the validity of the test kit evaluation and is still exceeded the requirements of the protocol for bovine milk where only single animal incurred samples are used for the evaluation of the kit. Sample of the goat milk were taken at 12 hour intervals and tested using both the BSDA and the Charm SL kit. Samples were collected from the animals until both tests gave negative results. The SL kit gave acceptable results with incurred goat milk. The results of the SL test were similar to those obtained from the BSDA and from earlier goat milk studies.

Based on the data generated at the independent laboratory, it is recommended that the Charm SL Beta-Lactam test kit for Amoxicillin, Ampicillin, Ceftiofur, Cephapirin and Penicillin G is suitable for testing raw commingled goat milk. The performance of the kit for testing goat milk was similar to the performance of the kit for testing bovine milk. A copy of the modified labeling for the kit is attached.

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